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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,054	10/15/2003	James E. Brown	DURE-045	7524

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EXAMINER

MEHTA, BHISMA

ART UNIT PAPER NUMBER

3767

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/687,054

Applicant(s)

BROWN ET AL.

Examiner

Bhisma Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "30" has been used to designate both a valve neck and an actuation/activation device. Similarly, the following reference characters have also been used to designate different parts: 32 (top cone and trocar), 34 (meniscus and handle), 44 (shoulder and proximal end of trocar), 46 (neck portion and distal end), 42 (body portion, first load member, and light spring), 40 (helical channel and load spacer), 38 (o-ring, second load member, and heavy spring), 36 (cylindrical ring and push rod), 48 (head portion and lever), and 56 (tubular segment and trocar). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 54. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in

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compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the retaining mechanism must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

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application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The disclosure does not mention a resistive load means comprising a spring where the spring has a first resistive load level and a second resistive load level. Also, the specification does not mention a resistive load of about 1 to 30 lbft.
5. The disclosure is objected to because of the following informalities: In lines 10-11 of page 11, reference character 30 is used for a valve neck and for a bottom assembly. Reference character 18 is used for a plunger in line 4 of page 11 and for a plug in line 24 of page 11. In lines 16-19 and lines 23-25 of page 13, the reference to "lbf" is unclear, as this does not appear to be a recognized unit.

Appropriate correction is required.

Claim Objections

6. Claims 1-10 are objected to because of the following informalities: Claim 1 recites the limitations "said device" in lines 3-6 and in line 13 and "said device function"

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in lines 14-15. It should be noted that neither the device nor the device function have been positively recited. Claim 3 recites the limitations "said second resistive load" in line 1 and "said first resistive load" in lines 2-3. Claim 7 recites the limitation "said device" in line 1. There is insufficient antecedent basis for these limitations in these claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In claims 1 and 6, it is unclear how the device function is being activated by applying sufficient force to overcome a first resistive load level of the resistive load means and what is meant by the device function being activated. Also, the specification does not clearly describe what the function of the device is and how the activation of the device is accomplished by pushing, pulling, or turning a portion of the device when the device is in the claimed apparatus. In claim 6, it is unclear what is meant by a resistive load of 0.5 to 3 lbft or 1 to 30 lbft. It is not clear how the resistive load of the load members is and how it has been calculated.

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9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 2, 8, and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 2, it is unclear how the resistive load means comprising a spring can have a first resistive load level and a second resistive load level. In claim 8, it is unclear if the implant-retaining member being claimed is referring to the retaining mechanism recited in claim 1 or if an implant-retaining member in addition to a retaining mechanism is being claimed.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al (U.S. Patent No. 6,530,875) in view of Antaki et al (U.S. Patent No. 6,270,472). Taylor et al disclose an apparatus having an elongated tubular member (32) with a lumen extending from a proximal end to a distal end, a retaining mechanism (98 or 100) for retaining a device (60), a rod (44) positioned within the lumen and being translatable within the lumen, and a locking mechanism (62) for locking onto the rod. The device (60) is activated by being pushed by the rod. The retaining mechanism or

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implant-retaining member (98 or 100) is in the form of a leaf-spring as seen in Figures 4B and 4C. Taylor et al also disclose a kit in the form of the apparatus and drug delivery devices (60). Taylor et al disclose the apparatus substantially as claimed. However, Taylor et al do not disclose a resistive load means positioned in the lumen which is adapted to contact the device in the lumen. Antaki et al teach an elongated tubular member (39) having a resistive load means (83, 85) in the form of springs, a rod (47) located proximal to the resistive load means, and a locking mechanism (49) for locking onto the rod. In lines 56-65 of column 9, Antaki et al teach that the resistive load means comprises a first load member (85) and a second load member (83) where the second load member is stronger than the first load member, thus the resistive load level of the second load member is greater than the resistive load level of the first load member. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the lumen of Taylor et al with the resistive load means as taught by Antaki et al as both Taylor et al and Antaki et al disclose apparatus to deliver implants into a patient's body and Antaki et al disclose that it is well known to use the resistive load means to deliver an implant into the body. As to claims 5 and 6, Even though Antaki et al teach that the second load member is stronger than the first load member, Antaki is silent on the specific of the resistive loads of the load members and by how much the second load member is stronger than the first load member. The parameters of resistive load are deemed matters of design of choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lifshey (U.S. Patent No. 5,279,555) discloses an injector for delivering implants with a rod or push member. Steube et al (U.S. Patent No. 6,447,483) disclose an injector for delivering implants with two springs.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Mon. through Fri., 7:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


BM

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

